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Mad Cow Disease: Agricultural Issues for Congress

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Mad Cow Disease: Agricultural Issues for Congress

SUMMARY

Most countries banned U.S. beef after the December 2003 report of BSE (bovine spongiform encephalopathy, or mad cow disease) in a Canadian-born cow found in Washington state. Several of these markets have partially reopened. However, Japan and Korea, which together had purchased 61% (by value) of all U.S. beef exports in 2003, remain closed. Further progress was clouded by reports of BSE in the first U.S. native-born cow, first tested in November 2004 but not confirmed until June 2005.

Japan says it is working to finalize its rules to admit U.S. beef, in order to implement an October 2004 framework agreement to restart trade. A year later, the changes are not yet final. Reflecting U.S. frustration, the Senate on September 20, 2005, adopted a floor amendment to bar a rule USDA proposed in August enabling Japan to export beef to the United States unless Japan has opened its markets for U.S. beef. On the House side, a resolution (H.Res. 137) has been introduced urging economic sanctions if Japan does not begin to accept U.S. beef.

Canada's own first native BSE case was reported in May 2003. So far, a total of five native cases have been found in North America (one U.S.-born and four Canadian-born cattle). BSE-contaminated feed is considered the likely cause of infection in all cases.

USDA said that total U.S. beef exports in 2004 reached only 17% of their 2003 level of about 2.5 billion pounds. However, strong domestic demand and tight cattle supplies kept U.S. cattle prices relatively high throughout 2004 and the first half of 2005.

Some Canadian beef has been permitted into the United States since August 2003.

USDA published a final rule, on January 4, 2005, that is also now allowing younger live cattle and additional Canadian ruminant products to enter. A U.S. judge's March 2, 2005, preliminary injunction to block the rule was reversed by an appeals court on July 14, 2005.

In Congress, the Senate on March 3, 2005, passed a joint resolution (S.J.Res. 4) to overturn the Canada rule. However, a resolution must pass the House (where similar H.J.Res. 23 was introduced) and be signed by the President, which most observers believe is unlikely. Several other BSE-related measures have been introduced recently, including H.R. 187, H.R. 384, H.R. 1254, H.R. 1256, H.R. 2068, H.R. 3170, H.R. 3931, S. 73, S. 108, S. 294, S. 1300, S. 1331, S. 1333, and S. 1779.

USDA and other experts contend that the risk to human health from one or a few U.S. BSE cases is minimal. Nonetheless, USDA stepped up efforts to improve BSE safeguards, including banning downer (nonambulatory) cattle from human food; keeping from the food supply additional higher-risk animal parts; working on a national animal identification system for disease purposes; and increasing funds for BSE-related activities.

The Food and Drug Administration (FDA) on October 6, 2005, proposed long-awaited rules to further restrict the cattle parts which may be used in all animal feeds.

After 70 weeks, nearly 485,000 cattle had been tested, all but one negative for BSE, under an expanded surveillance program. The positive was a sample that had tested negative in November 2004 but which later was determined to be positive using different testing methods. This brought renewed scrutiny of USDA testing.

MOST RECENT DEVELOPMENTS

On October 6, the Food and Drug Administration (FDA) published a long-awaited proposed rule intended to strengthen its existing feed restrictions, which now prohibit most mammalian protein to be fed to ruminants. The proposal would ban, from all animal feeds, certain higher-risk cattle parts (mainly brains and spinal cords from cattle 30 months and older and from those not passed for human food). Comments are due December 20, 2005.

BACKGROUND AND ANALYSIS

Introduction¹

Bovine spongiform encephalopathy (BSE), widely known as mad cow disease, is a degenerative, fatal disease affecting the nervous system in cattle. Worldwide, BSE has been found in 187,000 animals, 183,000 of them in Great Britain, where it was first detected in 1986. (Most of the rest occurred elsewhere in Europe.) Reported cases of BSE have declined steeply since 1992, when they reached an annual peak of 37,000 in Great Britain.

In North America, five native cases of BSE have been reported, all between May 2003 and June 2005. Four were born in Canada; the fifth animal was U.S.-born. In 1993, Canada also reported BSE in an animal that had been imported in 1987 from Great Britain.

The predominant theory among scientists is that a “proteinaceous infectious particle” or “prion,” for which no treatment or preventive vaccine exists, causes BSE, which they believe is transmitted to other cattle through feed containing BSE-infected protein by-products. BSE cannot be detected until symptoms (e.g., neurological abnormalities; inability to stand or walk) appear, nor can it be confirmed until brain tissue is tested. Estimates of average incubation for BSE symptoms in cattle range from two to eight years.

Until December 2003, tests had not found BSE in a U.S. herd. Nonetheless, scientific uncertainty about its cause and transmission had spurred U.S. precautionary actions in recent years aimed at confirming BSE’s continued absence and preventing imports of livestock or animal products that could carry it. Other BSE-like animal diseases, collectively called transmissible spongiform encephalopathies (TSEs), have long been present here. They include scrapie in sheep and chronic wasting disease (CWD) in deer and elk.

A rare but fatal human disease, Creutzfeldt-Jakob disease (CJD), also is known to occur in the United States, where it normally strikes about one in one million people yearly. Following the British BSE outbreak, a new-variant CJD (vCJD) was identified and is believed to be transmitted to humans mainly through consumption of cattle products contaminated with the BSE agent. About 160 people have been diagnosed with vCJD since 1986, most of them in Great Britain.

¹ Except where noted, sources primarily are USDA daily briefings and backgrounders on BSE, which are available through the USDA website at [<http://www.usda.gov>].

U.S. BSE Cases

December 2003. USDA announced on December 23, 2003, that brain samples taken from a Holstein dairy cow in Washington State had tested positive for BSE, the first such U.S. case. While emphasizing that the risks to food safety and human health were minimal, U.S. officials initiated standing BSE response plans including an extensive investigation that eventually led to the precautionary killing of about 700 cattle and the testing for BSE of 250 of them. No other cases were found during this investigation, led by USDA's animal health agency, the Animal and Plant Health Inspection Service (APHIS).

Officials traced the BSE cow to its birthplace in an Alberta, Canada herd in April 1997. It is believed to have entered the United States with 80 other dairy cattle from the same Alberta herd in September 2001; the cow reached a 4,000-head dairy herd in Mabton, Washington, in October 2001. The cow likely was infected in Canada by eating contaminated feed before a 1997 ban on feeding most mammalian proteins to cattle became effective, according to APHIS. U.S. authorities eventually located 28 of the 80 animals at eight different facilities, mostly in Washington. None of those found tested positive for BSE.

November 2004. On June 24, 2005, the Secretary of Agriculture said tests had confirmed the first case of BSE in a U.S.-born animal. Screening tests had first been conducted on this cow in November 2004, and at that time were reported as "inconclusive" (i.e., possibly positive) for BSE. Later in that month, USDA announced that the animal was negative for BSE; officials based this announcement on a follow-up analysis of tissue samples using the so-called "IHC" or immunohistochemistry test method. In early June 2005, prodded by the USDA Office of Inspector General, department scientists retested a sample from the cow using another confirmatory test, the "Western blot." The retested sample showed a positive reaction for BSE. Both the IHC and Western blot tests are recognized by the international organization for animal health, known by its French acronym, OIE. Brain tissue was then taken for final confirmatory testing at the BSE World Reference Laboratory in Weybridge, England. The Secretary's June 24 announcement was based on the results of the Weybridge testing, plus follow-up testing by USDA's Ames laboratory.

Department officials have stated that the cow in question was a 12-year-old Brahma cross beef cow from a Texas farm, initially reported to be nonambulatory. The animal was sampled at a plant that renders dead, dying, diseased, or disabled animals for non-human uses such as pet food, USDA said, adding that no material from the cow entered the food or feed supply. The epidemiological investigation, completed in late August 2005, attempted to trace all adult animals that left the index farm (the Texas ranch) after 1990 and all progeny born within two years of the BSE cow's death. Sixty-seven animals still on the index farm were killed and tested, all negative for BSE. USDA determined that 200 animals of interest had left the farm, 143 of which were slaughtered. Only two others were found alive; one was not tested because its age ruled it out as a suspicious animal, and the other tested negative. Of the rest, 34 were presumed dead, one known dead, and 20 were untraceable. USDA also was interested in two calves born to the BSE cow, but due to recordkeeping gaps, it had to trace a total of 213 calves to try to eliminate the calves of interest. None were found alive to test (most were fed and slaughtered for beef).

What Is the BSE Risk in the United States?

Harvard Risk Analysis. A USDA-funded study issued in November 2001 by the Harvard Center for Risk Analysis, based on a three-year risk analysis, stated in part that “BSE is extremely unlikely to become established in the United States.... Similarly there appears to be no potential for an epidemic of BSE resulting from scrapie, chronic wasting disease, or other cross-species transmission of similar diseases found in the U.S.... If the disease does indeed occur spontaneously in cattle, as some have suggested, it would result in one to two cases per year with little spread. Only a small amount of potentially dangerous tissues would reach the human food supply and be available for possible human consumption.”

After a BSE case was found in Canada in May 2003 (see below), USDA asked Harvard to reassess the risk. Harvard responded that although “the possible introduction of BSE into the U.S. from Canada cannot be dismissed,” the likelihood is very low, and U.S. protective measures by now would have contained any possible spread. The Harvard study is based on a computer simulation, which several critics indicate could be based upon arguable assumptions. The study authors acknowledge that their model is “not amenable to formal validation because there are no controlled experiments in which the introduction and consequences of BSE introduction to a country has been monitored and measured.” But the authors assert that they tested the model’s predictions against an actual small BSE outbreak in Switzerland and found them “reasonably close to empirical observations.”

However, the Harvard reassessment also noted that a group of cattle imported into Canada from the United Kingdom in 1993 included one that was found to have BSE. The report observed that if additional animals in this group harbored BSE, were slaughtered and rendered, infectivity may have been introduced into the Canadian and U.S. cattle feed supplies before the 1997 feed ban was implemented in both countries. “If additional animals were infected, they may have been exported to the U.S. as well.... [It] appears that any related introduction of BSE into the U.S. from Canada would have been due to the import of either infected animals or contaminated feed. Imports are a plausible source of introduction of BSE into the U.S. from Canada because the American and Canadian beef industries are closely linked. During the previous five years, the U.S. on average imported over 1.2 million cattle and 185,000 tons of feed annually from Canada.”²

International Review Team (IRT). After the U.S. BSE discovery in December 2003, USDA asked a panel of experts to examine the government’s response, and its findings were released on February 4, 2004. Although the infected animal may be the only one from the 81-cow herd that survived to adulthood, and its birth cohorts “do not represent significant risk,” the panel concluded, “it is probable that other infected animals have been imported from Canada and possibly also from Europe. These animals have not been detected and

² Joshua Cohen and George M. Gray, *Evaluation of the Potential Spread of BSE in Cattle and Possible Human Exposure Following Introduction of Infectivity into the United States from Canada*, pp. 1-2 (undated 2003 report), Harvard Center for Risk Analysis, School of Public Health, [http://www.aphis.usda.gov/lpa/issues/bse/harvard_10-3/text_wrefs.pdf]. The Harvard risk analysis considered import as well as domestic practices in its assessment. Both the GAO and the Harvard study did note that noncompliance with the feed ban could occur at many points in the feed chain. Moreover, FDA does not actually test the feed for prohibited material.

therefore infective material has likely been rendered, fed to cattle, and amplified within the cattle population, so that cattle in the USA have also been indigenously infected.”³

The panel concluded that USDA’s epidemiological investigation and the tracing and recall of meat and byproducts had conformed to international standards insofar as possible. However, it said that an “appropriate” national ID system was needed to enable suspect animals to be traced more quickly; and that USDA should expand testing to determine the prevalence of any BSE in the United States. The IRT also observed that the partial ruminant to ruminant feed ban now in place is “insufficient,” and that a complete ban on the feeding of all mammalian and poultry byproducts to cows and other ruminants is justified. (Some meat industry officials had criticized the IRT findings because, they asserted, the team had based its observations on the situation in Europe, where BSE has been far more prevalent.)

U.S. BSE Safeguards

Import Restrictions. APHIS has an import ban on live ruminants (cows, sheep, goats) from countries with known BSE cases (started in 1989); an import ban on ruminant meat and meat products from BSE countries (since 1991); and a prohibition on importing ruminants and most ruminant products from all of Europe (since 1997). In late 2000, USDA prohibited imports of all rendered animal protein products, regardless of species, from Europe out of concern that feed of nonruminant origin was potentially cross-contaminated with the BSE agent. Under the FSIS foreign inspection program, no establishments in countries where BSE has been found can ship beef to the United States.

The exception now is Canada, which USDA contends has a science-based approach to BSE safety. This approach appears consistent with new BSE guidelines adopted in May 2005 by the World Organization for Animal Health (or OIE, the French acronym). A key assumption for this guidance is that countries with strong safeguards should not be penalized merely because rigorous testing has found an acceptably low number of BSE cases.⁴

Targeted Domestic Surveillance. Among other duties, meat inspectors examine every animal entering slaughter plants. FSIS indicates it has not permitted cattle showing suspicious neurological symptoms to be slaughtered for human consumption. It has sent brain samples from such animals to an APHIS laboratory in Ames, Iowa, as part of what USDA called a “targeted surveillance approach designed to test the highest risk animals, including some but not all downer (nonambulatory) animals, those that die on the farm, older ones, and animals exhibiting signs of neurological distress.”⁵ The program had grown

³ *Report on Measures Relating to Bovine Spongiform Encephalopathy (BSE) in the United States*, at [http://www.aphis.usda.gov/lpa/issues/bse/US_BSE_Report.pdf]. The panel, a subcommittee of the Secretary’s Foreign Animal and Poultry Disease Advisory Committee, included two Swiss experts and one each from the United Kingdom, New Zealand, and the United States, the latter Dr. Will Hueston, a veterinarian who is Director of the Center for Animal Health & Food Safety at the University of Minnesota and a former APHIS official.

⁴ See the OIE website at [http://www.oie.int/eng/info/en_statesb.htm].

⁵ USDA backgrounder on BSE, July 10, 2003. For more details, see CRS Report RL32922, *Meat and Poultry Inspection: Background and Selected Issues*, by Geoffrey S. Becker.

steadily from a few thousand animals tested annually in the mid-1990s to about 20,000 cattle in each of FY2002 and FY2003, out of about 35 million slaughtered each year.

Critics argued that this surveillance was inadequate to detect BSE. Some proposed that testing should approximate levels in Europe, where policy calls for testing all cattle over 30 months old, or in Japan, which claims to test all cattle for slaughter. USDA argued that its program was testing many more animals than recommended by the OIE, and that because surveillance is targeted to test higher-risk animals, it could effectively detect BSE if it is present in the bovine population at a level of one in one million adult animals.

USDA had intended to test 40,000 cattle in FY2004, but in June 2004 it began a greatly expanded, 12-18 month effort to determine the extent, if any, of BSE in higher-risk cattle, which it estimated to number 446,000. Targeting higher-risk animals, USDA contracted with a network of participating state veterinary laboratories to conduct screening using rapid test kits, in addition to using its own Ames, Iowa, facility. Samples are collected from slaughter establishments, on farms, at rendering facilities, cattle marketing sites, and veterinary and public health laboratories. Any rapid test not negative for BSE (“inconclusive” in USDA’s parlance) is sent to the national reference laboratory in Ames for confirmatory testing, which takes longer but is considered more reliable. After 70 weeks of testing through October 2, 2005, nearly 485,000 cattle had been tested, all but one negative for BSE.⁶ (USDA had announced it would also test 20,000 apparently healthy cattle, but that portion of the special program had not been started as of October 1, 2005.)

Testing Issues. BSE testing had been the focus of a joint hearing held July 14, 2004, by the House Government Reform and Agriculture Committees. USDA’s Inspector General (IG) testified on a draft OIG report which cites a number of limitations in the department’s expanded surveillance plan. For example, testing results may be unreliable because the plan: is not truly random because participation is voluntary; assumes that BSE is confined only to the high-risk cattle population while other studies show that healthy-looking animals could have BSE; does not include a process for obtaining animals that die on farms; cannot obtain a statistically appropriate geographical representation of the cattle population; does not allow APHIS to find and test enough cattle in the high-risk population. The final OIG report, issued in late August 2004, generally paralleled the preliminary findings.

USDA officials had defended their testing, noting among other things that the OIG observations were based on the plan before it was implemented and that many of the report’s recommendations have been addressed. APHIS is receiving a representative mix of samples from all locations, reaching deeply into the higher-risk cattle population, and the statistical basis for the sampling is sound, officials asserted. They added that adjustments have been made as the result of ongoing assessments of the program.

After it was widely reported that USDA had failed to test a suspicious cow in Texas in late April 2004, the department announced revisions in its BSE sampling procedures. (The cow was condemned so its meat never entered the food supply, USDA said.) USDA stated that it was retraining inspectors, mandating that FSIS rather than APHIS personnel

⁶ The other U.S. case (December 2003) emerged during routine BSE testing prior to this intensive surveillance program. Test results are posted at [http://www.aphis.usda.gov/lpa/issues/bse_testing/].

collect brain samples, and requiring that all cattle condemned antemortem (before slaughter for human food) be tested for BSE, not just those with suspicious symptoms. In a review of the Texas case, OIG found that officials had erred — but did not engage in intentional misconduct or knowingly provide misleading information — in failing to test the suspicious Texas cow. OIG reached similar conclusions about how the department had characterized the Washington BSE cow as nonambulatory in December 2003.

It was OIG that in spring 2005 urged USDA to retest samples from a cow that was first suspected of BSE in a screening test in November 2004, but that later tested negative when USDA applied its so-called “gold standard,” or IHC test method. After its IHC test came back negative for BSE, USDA did not run the other internationally recognized confirmatory test, the Western blot. (It did run the Western blot test to confirm the BSE-positive result in December 2003, however.)

OIG wanted the tissue retested because of its concerns about the original testing procedures (for example, the sample should not have been frozen; and there were paperwork reporting problems). This OIG-requested retesting in early June 2005 was done by USDA scientists — reportedly without the prior knowledge of the Secretary of Agriculture — using the Western blot. When this test showed the presence of BSE, USDA took samples from the animal to the World Reference Laboratory in England.

Weybridge conducted a series of analyses on the samples, all except one of which detected BSE, including another IHC test. The Secretary of Agriculture explained that the positive IHC test by Weybridge used a different procedure than the one used in November 2004 by USDA at Ames. A Weybridge scientist, Dr. Danny Matthews, confirmed that “there are no two laboratories around the world that are using identical IHC methods and not a single test that you can take off the shelf,” so that tests may not perform equally.⁷

USDA also revealed on June 24 that a USDA laboratory had actually found possible BSE in the animal last year when it applied an “experimental” version of the IHC test. But they asserted that the laboratory had not reported this result because the test was not a proven one. This information, and the positive BSE confirmation by Weybridge, provoked strong criticism by consumer groups and several Members of Congress. They have expressed renewed skepticism about the adequacy of USDA’s testing methods and procedures; and about department officials’ willingness to communicate all relevant information about BSE in the United States.

Secretary Johanns, who replaced Ann Veneman as Secretary earlier in 2005, defended USDA’s surveillance program, stating: “Science is ever evolving. It is not static. And as we learn more we apply the knowledge.” USDA is carefully reviewing its testing to ensure that it is “in line with the very latest science,” he said, adding, “perhaps the most important thing to remember is that we’ve only needed this test three times since our enhanced surveillance began.” Nonetheless, APHIS has again revised its testing protocol: for any future

⁷ Transcript of media conference, June 24, 2005, at [<http://www.usda.gov/wps/portal/usdahome>]. For an explanation of the two OIE-approved tests, see the June 2005 APHIS factsheet at [http://www.aphis.usda.gov/lpa/pubs/fsheet_faq_notice/faq_BSE_confirmtests.pdf].

inconclusives, USDA will run both an IHC and Western blot confirmatory test. If results from either one are positive, the sample will be considered positive for BSE.⁸

On July 27, 2005, USDA had reported that another cow tested suspiciously. The animal was reported to be at least a 12-year-old cow that was experiencing calving complications. A private veterinarian took a brain sample from the animal — whose carcass was destroyed — in April 2005 but did not submit the sample to USDA for testing until July 2005. APHIS officials stated that the veterinarian had preserved the sample and simply forgot to send it for testing earlier. USDA tested the sample using the IHC method (the Western blot and rapid test could not be performed due to the way the sample was preserved) and found what it called a “non-definitive” result. However, after further confirmatory tests by APHIS and Weybridge, USDA announced on August 3, 2005 that the cow was negative for BSE.⁹

Domestic Cattle “Feed Ban”. The U.S. Food and Drug Administration (FDA), which regulates animal feed ingredients, banned most mammalian proteins from cattle feed on August 4, 1997.¹⁰ Exceptions have existed for blood and blood products; gelatin; inspected, processed, and cooked meat products for human consumption (such as restaurant plate waste); milk products; and products containing pork and equine proteins only. Most mammalian proteins can still be fed to other animals such as pigs, poultry, and pets. To ensure compliance, FDA enforcement includes education as well as inspections of the estimated 264 renderers (firms that prepare animal parts not destined for human food), and of all known feed mills (as many as 9,240 or more, according to the agency).

Some industry groups argue that existing feed restrictions are sufficient to prevent any spread of BSE, and that further actions (like removal of higher-risk cattle parts from all animal feed; see below) both are unnecessary and would cost the industry many hundreds of millions of dollars in lost market revenues and waste disposal expenses. Critics, however, contend that stronger actions are needed to protect the feed supply — and ultimately cattle and beef consumers — from BSE contamination.

The Government Accountability Office (GAO) has been critical of the enforcement of the current FDA ban. Most recently, a February 2005 GAO report concluded that FDA had made improvements in its management of the feed ban, but that program weaknesses continue to limit its effectiveness, placing U.S. cattle at risk of spreading BSE. Among the weaknesses cited by GAO are that FDA has no uniform approach for identifying all the additional feed manufacturers, on-farm mixers, and other feed industry businesses beyond the approximately 14,800 firms it has inspected so far; that it has not reinspected approximately 2,800 of the firms it has inspected and does not know whether they use prohibited materials (i.e., cattle parts that might harbor the BSE agent) in their feed; that FDA has not required a warning label on feed for export even though it is not intended for

⁸ Transcript of media conference, June 24, 2005.

⁹ In an August 3, 2005, statement, APHIS Deputy Administrator John Clifford said: “The initial non-definitive result was caused by artifactual (artificial or untrue) staining and, while this staining did not resemble BSE, we felt the prudent course was to conduct the additional tests.”

¹⁰ See *CVM and Ruminant Feed (BSE) Inspections*, at [<http://www.fda.gov/cvm/RuminantFeedInspections.htm>]. For background on the rendering industry, also see CRS Report RS21771, *Animal Rendering: Economics and Policy*, by Geoffrey S. Becker.

cattle and other ruminants; and that it has not always alerted USDA and the states when it learns that cattle may have been given prohibited feed.

In July 2003 and January 2004, FDA reported that feed industry compliance with the ban had reached 99%. However, that may be misleading, because the compliance rate was last based on inspections of only about 570 firms, GAO reported. The GAO report added that FDA does not include all serious violations in the calculations because it reclassifies firms as being in compliance once they correct violations, no matter how long a problem existed, among other problems with the data.

FDA had promised in January 2004 that it would strengthen its feed controls, saying that it intended to ban from ruminant feed the following materials: ruminant blood and blood products, poultry litter (which can contain spilled feed that may contain ruminant material), and restaurant plate waste. Further, FDA said it would require feed mills to segregate ruminant and non-ruminant feed production lines/facilities if the mills use proteins prohibited in ruminant feeds. The agency promised to step up its inspections of the mills and of renderers to ensure compliance.

On July 14, 2004, FDA published jointly with USDA an advanced notice of proposed rulemaking (ANPR). One section of the *Federal Register* notice asked for public input “on additional measures under consideration to help prevent the spread of BSE.” Significantly, the FDA stated in the rule that it “has reached a preliminary conclusion that it should propose to remove SRM’s from all animal feed and is currently working on a proposal to accomplish this goal.”

FDA published its long-awaited proposal in the October 6, 2005, *Federal Register* (pp. 58570-58601). The proposed rule would prohibit use of the following cattle parts in any type of animal feed: brains and spinal cords of cattle 30 months and older and of any cattle not inspected and passed for human consumption; entire cattle carcasses not passed for human consumption if the brains and spinal cords have not been removed; tallow derived from prohibited materials if it has more than 0.15% insoluble impurities; and mechanically separated beef derived from prohibited materials.

FDA’s preamble stated that the proposal addresses concerns that high-risk material, because of its presence in non-ruminant feeds, can still be fed to ruminants. This is because of either cross-contamination during rendering and manufacturing, or of intentional or unintentional feeding of high-risk material to cattle on farms — where monitoring compliance is difficult at best. The proposal continues to permit in non-ruminant feed some of the SRMs that are now banned from human food (e.g., distal ileum tonsils, other nervous tissue; see below). It also continues to permit, in ruminant feeds, the use of cattle blood and blood products, plate waste, and poultry litter.

Critics have argued that the U.S. plan therefore contains gaps that could still expose cattle, and ultimately humans, to unnecessary BSE risks. They note that Canada’s proposal to tighten animal feed regulations would be more restrictive than the U.S. proposal. FDA, relying on scientific risk assessments, said that brains and spinal cords alone account for 90% of BSE infectivity in cattle. So ensuring their removal will greatly reduce risks at an acceptable burden to the rendering, feed, and related industries.

(In the 109th Congress, S. 73 would explicitly define and ban SRMs from all animal feeds.)

Meat Inspection Changes. On December 30, 2003, USDA announced steps to strengthen FSIS-regulated practices where cattle are slaughtered and processed:

Downers. USDA banned all nonambulatory cattle from slaughter establishments, to ensure that they cannot be passed for human food use, though they still can go to rendering plants for other uses, including nonhuman food. The number of such animals was estimated by the Secretary to be 150,000-200,000 out of the roughly 35 million U.S. cattle slaughtered yearly. The downer ban has been among the most controversial changes for producers, who say they incur large losses when they cannot sell cattle unable to walk for reasons unrelated to BSE (e.g., a broken leg). (Interim final rule, January 12, 2004, *Federal Register*.)

Specified Risk Material (SRM). USDA declared as SRM (and thus unfit for human food) the skull, brain, trigeminal ganglia, eyes, vertebral column, spinal cord, and dorsal root ganglia of cattle over 30 months, and the small intestine of cattle of all ages. (Tonsils already were considered inedible for human food.) An SRM declaration prohibits the use of these cattle parts in the human food supply. The rule requires cattle packers to develop and implement procedures to remove and dispose of SRMs so that they cannot enter the food chain. (Interim final rule, January 12, 2004, *Federal Register*.)

FDA published, in the July 14, 2004, *Federal Register*, an interim final rule to prohibit higher-risk material from the human foods, dietary supplements, and medicines that it regulates. The materials are those banned under USDA rules: SRMs, which are brain, skull, eyes, trigeminal ganglia, spinal cord, vertebral column and related tissue, and dorsal root ganglia from animals over 30 and tonsils and distal ileum of all cattle; mechanically separated beef; and material from nonambulatory cattle. An accompanying proposed rule would require that affected food manufacturers maintain records for two years to ensure compliance.¹¹

Advanced Meat Recovery (AMR). AMR mechanically removes muscle tissue from bone, and the paste-like tissue can be labeled as “meat.” FSIS previously had regulations to prohibit such products to be labeled as “meat” if they contain spinal cord. This newer rule expands that prohibition to include additional nerve tissue. Also, AMR no longer can be used for cattle 30 months and older. Earlier FSIS sampling had found nervous system tissue in about a third of AMR beef. (Interim final rule, January 12, 2004, *Federal Register*.)

“Test and Hold”. All products from a carcass being tested for BSE must be held until USDA confirms that the BSE test is negative. (Notice, January 12, 2004, *Federal Register*.)

¹¹ Under this rule, FSIS had required removal of the entire small intestine, even though the distal ileum was the only portion where BSE infectivity has been confirmed. However, FSIS published an interim rule in the September 7, 2005 *Federal Register* to permit plants, beginning on October 7, 2005, to remove the distal ileum (defined to be at least 80 inches) and to utilize the rest of the small intestine for food. (FDA published a similar rule on the same day for the products it regulates.) These actions were in response to industry comments that technology exists to effectively remove the distal ileum.

Stunning. USDA banned air-injection stunning, to ensure that brain pieces are not dislocated into carcass tissues during slaughter. USDA stated that this method was now rarely used. (Interim final rule, January 12, 2004, *Federal Register*.)

Noncompliance Reports. In response to Freedom of Information requests, USDA released records showing that more than 1,000 “noncompliance reports” were issued to packers over 17 months following issuance of these new inspection rules. About 400 of the violations were due to procedural shortcomings such as plants’ failure to reassess and rewrite their safety procedures to encompass SRM removal, and another 250 were related to specific instances of SRM violations such as not cleaning equipment properly, a spokesman with Public Citizen told *Food Chemical News*. A representative of the American Meat Institute indicated that the noncompliance issues generally occurred while plants were integrating the new rules, and posed minimal risk to food safety.¹² The trade newsletter *Cattle Buyers Weekly* characterized the 1,000 noncompliance reports as “near 100% compliance” with the new SRM rules, because the number represented 0.002% of the 46 million cattle that were processed during the period. Immediate remedial action was taken in every instance, and no banned materials entered the food supply, the publication stated, citing USDA.¹³

Animal Identification and Traceability. Secretary Veneman also said in January 2004 that USDA would “begin immediate implementation” of a national animal ID system. A government-industry committee already had been working on the framework for a system, and it earlier had anticipated that states would have individual IDs in place for cattle for interstate movement by July 2005. In August 2004, USDA announced it was signing cooperative agreements with 29 states and tribal agencies to receive \$11.64 million to register premises, collect data, and test ID technologies. In June 2005, USDA announced said that it would disburse another \$14.3 million to continue premises registration efforts. APHIS now projects that all states will have the capability to register individual premises (but not yet animals) by this year, and that individual animal numbers will also become available this year. But a national system may not be fully in place until 2009.¹⁴

Some argue that USDA, which has embarked on an all-farm species approach, is progressing too slowly; the National Cattlemen’s Beef Association (NCBA), for example, is now proposing to establish a privately operated system that could be fully operational by October 2006. Interestingly, the BSE issue has helped to accelerate animal ID, originally intended to track mainly contagious diseases — which BSE is not.

In Congress, several Members have complained that lack of a nationwide system has hindered the investigations into the U.S. BSE cases. H.R. 1254 would require the establishment of a nationwide electronic animal identification system. H.R. 1256 deals with protecting the information provided by producers from unauthorized scrutiny and use. Additional animal ID bills are anticipated. H.R. 3170 would create a “Livestock Identification Board” with voting members from industry to oversee a national program, and the House Agriculture Committee has held hearings on the issue, including a privately-held

¹² *Food Chemical News*, August 22, 2005.

¹³ “Packers Comply With SRM Removal,” *Cattle Buyers Weekly*, Aug. 22, 2005.

¹⁴ For updates on USDA’s animal ID activities, including information on its strategic plan for an ID program, see [<http://animalid.aphis.usda.gov/nais/index.shtml>].

system. (See CRS Report RL32012, *Animal Identification and Meat Traceability*, by Geoffrey S. Becker.)

Funding. The Administration's FY2006 budget, released in early 2005, requests a total of \$66 million for USDA's BSE-related activities, including \$33 million to continue work on an animal ID program, \$21 million for BSE testing/surveillance, and \$12 million for research. Total USDA spending for BSE in FY2005 is estimated at \$123 million, of which \$69 million was for BSE testing (and most of that for the special surveillance program noted above), \$49 million to launch the animal ID effort, and \$3 million for research. Much of the FY2005 funding was through transfers from the Commodity Credit Corporation (CCC) account rather than through direct appropriation by Congress. USDA's BSE spending in FY2004 was an estimated \$51 million. Additional BSE amounts are spent through FDA and other agencies. The FDA requested for FY2006 a total of nearly \$30 million. The FY2006 USDA appropriation (H.R. 2744), passed by the House on June 8, 2005, and the Senate on September 22, 2005, and awaiting conference, generally covers these requests.

Industry Economic Implications

Cattle production is the largest single segment of U.S. agriculture (accounting for 20% of U.S. farm sales annually). Exports of U.S. beef and other cattle products are viewed as critical to long-term market growth. The value of beef and beef variety meat exports was estimated by USDA to be \$3.1 billion in 2003 (or about 10% of farm value for cattle/calves). Four countries bought approximately 90% of these exports: Japan (37%), South Korea (24%), Mexico (20%), and Canada (10%).

Most importing countries halted imports of U.S. beef and cattle soon after the December 2003 U.S. BSE announcement. Mexico and Canada are now accepting some U.S. beef and veal. By early 2005, officials had reported progress toward regaining other markets, although the latest U.S. BSE announcement could complicate efforts to normalize trade. USDA estimated that U.S. beef and veal exports globally reached 461 million pounds in 2004, or 17% of the 2003 level of 2.523 billion pounds. USDA has predicted that unless more markets reopen, exports would reach only 615 million pounds in 2005.

Domestic cattle and beef prices by late 2003 had reached record highs due to a tight supply-demand situation. The immediate impact of the BSE case was reflected in a drop in cash prices for Nebraska steers from \$91 per 100 pounds (cwt.) to about \$75 per cwt. the following week. However, prices recovered substantially after January 2004. A decline in U.S. cattle inventories due in part to widespread drought conditions in cattle country, along with strong domestic demand for beef, kept farm prices relatively high during much of 2004.

USDA has reported that average U.S. fed steer (i.e., slaughter-ready cattle) prices were \$84.75 per cwt. for all of 2004. This is near the lower end of a USDA forecast, made just before the BSE case, of \$84-\$91 per cwt. The 2005 price forecast (as of September 2005) was \$84-\$86. Average fed steer prices were \$84.69 in 2003 and \$67.04 in 2002.

NCBA earlier in 2005 placed cattle producers' export-related losses at \$175 per head, or \$4.7 billion total. The U.S. Meat Export Federation (USMEF) has estimated that lost export premiums on the top 10 cuts exported were costing the beef industry about \$100 per

head or more than \$2.8 billion annually.¹⁵ The U.S. share of the world market for beef/veal exports declined from 18% in 2003, to 3%, according to USDA data.

In April 2005, Kansas State University (KSU) issued a study on the impact of the BSE situation on the U.S. beef industry. Based on a trade model it developed, KSU estimated that total U.S. beef industry losses due to the loss of beef and offal exports in 2004 ranged from \$3.2 billion to \$4.7 billion.¹⁶

Japan Trade Issues

Japan and Korea are considered vital to the long-term export picture. On October 23, 2004, U.S. and Japanese negotiators announced that they had made progress in negotiations to resume two-way beef trade. According to a joint statement, the United States would certify that only beef from cattle of 20 months or younger are shipped. (Roughly 70% of the 35 million U.S. cattle each year are believed by USDA to be 20 months of age or younger, but verifiable age records may only be available for anywhere from 10% to 25% of cattle, according to various estimates.) The United States also agreed to, among other things, an expanded SRM definition, to cover cattle of *all ages*. USDA's current SRM list is somewhat different and generally covers only cattle over 30 months. In addition, the United States said it would institute rulemaking on the conditions for resuming U.S. imports of Japanese beef (mainly specialty products like Kobe), which have been banned since September 2001, due to the emergence of BSE in Japan.

The announcement stated that the two countries would evaluate this interim system by July 2005 and modify it if appropriate. However, Japan, which has reported about 20 cases of BSE in its own cattle, has not yet accomplished what it maintains are all the necessary regulatory changes. These rules have involved many steps and a number of different agencies, including review by Japan's independent Food Safety Commission — which, according to press reports, has expressed some renewed concerns about U.S. testing. Although Japan implemented a policy change on August 1, 2005, that only its own cattle over 20 months of age must be tested, all local governments continue universal testing. Also, additional policy changes to actually allow imports of U.S. beef are not final. Most observers do not expect any U.S. beef to enter Japan before later in 2005 at the earliest.

USDA did publish in the August 18, 2005 *Federal Register* a proposed rule that would permit the importation of whole cuts of boneless beef from Japan, under specified conditions. (Previously, Japan had exported relatively small quantities of specialty beef like Kobe to the United States.) USDA said the proposal is in accord with OIE guidelines and is based on a risk analysis indicating that such cuts could be safely imported. However, some expressed frustration that the United States appeared to be acceding to the Japanese request without a coinciding move by Japan, where the BSE problem has been more pronounced. On

¹⁵ The NCBA figures were used at the House's March 1, 2005, hearing on BSE. Also, USDA held a roundtable on "The Safety of North American Beef and the Economic Effects of BSE on the U.S. Beef Industry," on June 9, 2005, in St. Paul. For more information, see the USDA website at [<http://www.usda.gov>], and also CRS Report RS21709, *Mad Cow Disease and U.S. Beef Trade*.

¹⁶ *The Economic Impact of BSE on the U.S. Beef Industry: Product Value Losses, Regulatory Costs, and Consumer Reactions*.

September 20, 2005, the Senate adopted a floor amendment to the FY2006 USDA appropriation (H.R. 2744) to bar implementation of the proposed a rule unless the President certifies to Congress that Japan has granted open access to Japanese markets for U.S. beef and beef products. The House version lacks the provision. Separately, pending H.Res. 137, introduced earlier in 2005 in the House, calls for economic sanctions against Japan if it does not permit U.S. beef. Continuing delays by the Japanese could encourage Members of Congress and some industry stakeholders to press harder for retaliation.

Canada Trade Issues

The BSE situation in Canada has weighed heavily on U.S. trade policy considerations. Some argue that too hastily expanding U.S. imports of beef and cattle from Canada, where four BSE cattle were born, will endanger the U.S. cattle herd and undermine negotiations with the Japanese. Others counter that USDA's steps to reopen the border for Canada demonstrate to other countries that the United States is acting on the basis of scientific evidence that Canada's safeguards are effective — and that others should do likewise.

May 2003 BSE Announcement. Canadian officials announced on May 20, 2003, that they had discovered BSE in an Alberta cow (later found to have been born in Saskatchewan or Alberta in early 1997). The cow's brain had been pulled for testing in late January 2003. No meat from the cow became human food, according to the Canadian Food Inspection Agency (CFIA). Canadian authorities focused on, among other causes, the slaughter and rendering into feed (at either a U.S. or Canadian plant) of some imported British cattle that included one with BSE that was found in 1993.¹⁷

January 2005 Announcements. Canada confirmed a second BSE case on January 2, 2005. The CFIA announced that the animal was an Alberta dairy cow born in 1996. On January 11, 2005, CFIA announced its third confirmed case, this in an Alberta beef cow born in March 1998 — six months after its feed ban was published. CFIA stated that no part of either animal entered the human food or animal feed supply.¹⁸ Government veterinary experts on both sides of the border agree that some additional BSE discoveries in older U.S. and Canadian cows are “not unexpected,” particularly in light of enhanced surveillance activities, and that Canada could have as many as 11 reported cases and still satisfy the U.S. criteria for a “minimal risk” country.

Canadian Feed Ban. However, the relatively younger age of one Canadian BSE cow added a new dimension to the issue. Canadian officials have stated that the cow most likely consumed BSE-contaminated feed sometime after its birth, indicating that farmers likely were still using the last of such prohibited feeds in the months following the ban. This time was well past the 60-day grace period that farmers were granted to use up existing feed stocks — and followed a much longer period prior to that when the rule was being proposed and explained to the feed industry and to cattle producers. In a February 2005 report, USDA

¹⁷ Harvard Center for Risk Analysis, *Evaluation of the Potential Spread of BSE in Cattle and Possible Human Exposure Following Introduction of Infectivity into the United States from Canada*, released October 2003, at [http://www.aphis.usda.gov/lpa/issues/bse/harvard_10-3/text_wrefs.pdf]. The review noted it is possible some infected Canadian feed also has entered the United States.

¹⁸ See [<http://www.inspection.gc.ca/english/anima/heasan/disemala/bseesb/bseesbindexe.shtml>].

concluded that the Canadian feed ban has been effective. CFIA issued its own findings on March 2, 2005, also reporting high adherence to the feed rule.¹⁹

Some critics remained skeptical of these findings, arguing among other things that the reviews were inadequate. For example, they relied largely on reviewing paperwork to ascertain compliance, and generally did not examine the ban's implementation by Canada's 246,000 livestock farms — including some 25,000 on-farm feed mills, these critics assert.

USDA Rulemaking to Readmit Canadian Beef and Cattle. In late May 2003, the United States had issued an interim final rule placing Canada under its standing BSE import restrictions — that is, all Canadian ruminants (cattle, sheep, goats, deer, elk, etc.) and ruminant products were prohibited from entering the United States. It began to ease that ban on August 8, 2003, when USDA announced that it would accept applications for permits to import selected ruminant products from Canada, including boneless beef from cattle under 30 months old and boneless veal from calves no older than 36 weeks at slaughter; and boneless sheep and goat meat from animals under 12 months old. The August 2003 announcement was not accompanied by formal rulemaking.

On November 4, 2003, USDA did publish in the *Federal Register* a proposed rule to change its standing BSE policy so as to allow imports of certain live ruminants and products from “minimal risk” regions, including Canada. Permitted would be imports of cattle for slaughter under 30 months old; sheep and goats for slaughter under 12 months; cervids (e.g., deer and elk) for immediate slaughter; and various other products from these animals.

Notwithstanding this proposal, APHIS already was beginning to gradually expand the list of allowable beef imports through periodic notices on its website, but not in the *Federal Register*. Ranchers-Cattlemen Action Legal Fund, United Stockgrowers of America (R-CALF USA), sued to stop these expanded imports, and, on April 26, 2004, a federal judge in Montana issued a temporary restraining order to halt the imports. Among other issues, the judge cited concerns about whether USDA followed appropriate rulemaking procedures.²⁰ USDA subsequently agreed that it would not allow beef and veal products beyond the types listed on August 15, 2003 (see above), until issuance of the final rule that was first proposed on November 4, 2003. USDA officials stated further that then-Secretary Veneman had been unaware that APHIS had expanded the list of eligible products after August 8, 2003.

The final version of the November 4, 2003, proposal was announced on December 29, 2004, several hours before Canada revealed its second possible BSE finding. The new rule was published in the January 4, 2005, *Federal Register*, to take effect March 7, 2005. Specifically, the rule creates a new category of “minimal risk” BSE regions — those in which BSE-infected animals have been diagnosed, but where sufficient regulatory measures have been in place to ensure that the introduction of BSE into the United States is unlikely. The rule further classifies Canada in this category, the first such region to qualify, based on what USDA declared was “a thorough risk analysis.” (In addition, a region with effective BSE

¹⁹ See USDA's *Assessment of the Canadian Feed Ban*, at [<http://www.aphis.usda.gov/lpa/issues/bse/CAN-FeedBanReview.pdf>], and CFIA's *Feed Ban Review*, at [<http://www.inspection.gc.ca/english/anima/feebet/rumin/revexa/revintroe.shtml>].

²⁰ *Ranchers Cattlemen Action Legal Fund USA vs. USDA* (CV-04-51-BLG-RFC).

regulatory measures that has never detected the disease, but cannot be considered BSE-free, can qualify as a “minimal risk.”) The rule makes the following products eligible for importation from Canada:

- Cattle and other bovines for feeding and for immediate slaughter. All cattle must be under 30 months of age and be slaughtered at less than 30 months. All cattle must be moved in closed containers, be tagged on the ear to enable traceback to their birth herds, and be accompanied by health and other information, among other requirements. Feeder cattle must be branded and can only be moved to a single feedlot, and from that lot directly to slaughter.
- Sheep and goats (ovines and caprines) for feeding and immediate slaughter, which must be under 12 months of age and slaughtered by 12 months. Similar movement and identification rules apply to these animals.
- Most meat from bovines, ovines, caprines, and cervids (deer, elk, etc.). This includes, for example, bone-in cuts and cuts from cattle over 30 months. (On March 11, USDA announced a delay in the part of the rule allowing beef from over-30-month-old cattle.)
- Certain other products and byproducts including bovine livers and tongues, gelatin, and tallow.

R-CALF USA again sued. The same federal judge on March 2, 2005, issued a preliminary injunction to halt implementation, and later set July 27, 2005, for a hearing on whether a permanent injunction should be granted. The judge stated in part that R-CALF had “demonstrated the numerous procedural and substantive shortcomings of the USDA’s decision to allow importation of Canadian cattle and beef. The serious irreparable harm that will occur when Canadian cattle and meat enter the U.S. and co-mingle with the U.S. meat supply justifies issuance of a preliminary injunction ... pending a review on the merits.”²¹

The Administration on March 17, 2005, appealed to the U.S. Court of Appeals for the Ninth Circuit. The appeals court ruled, on July 14, 2005, to stay (reverse) the lower court’s ban. In its opinion, issued on July 25, the three-judge appeals panel rejected each of the major grounds for the district court’s findings. Among the appeals court’s conclusions were that “... based on the low incidence of BSE in the Canadian herd, the numerous safeguards against BSE in this country, the lack of any Canadian cattle under 30 months of age found with BSE, and the lack of any case of vCJD attributable to Canadian beef, any increased risk to human and animal health created by the Final Rule is negligible.”²² Subsequently, the first load of Canadian cattle since May 2003 entered the United States on July 18, 2005.

Several agricultural leaders in Congress had earlier expressed their own support for the rule. For example, the House Agriculture Committee chairman had asserted that a continuing ban on the expanded beef and cattle imports was “... causing adverse economic harm to our processing industry which has grave long term implications for cattle producers. Moreover, the decision further undermines our nation’s credibility as we seek to eliminate non-tariff trade barriers around the world.” At its March 1, 2005 hearing, the panel heard

²¹ *Ranchers Cattlemen Action Legal Fund USA vs. USDA* (CV-05-06-BLG-RFC).

²² *Ranchers Cattlemen Action Legal Fund USA vs. USDA*, (No. 05-35264, DC No. CV05-006RFC), July 25, 2005. U.S. Court of Appeals for the Ninth Circuit.

testimony that in 2004 Canada had increased its cattle processing capacity by 22%, as an alternative to shipping them to the United States. This had put many U.S. packers, particularly those who relied on Canadian cattle to supply their plants, at a great disadvantage, it was argued.

Others have defended USDA's assertion that — because Canada has in place safeguards that are at least equivalent to those of the United States, and because the North American market has become an integrated one — the rulemaking is reasonable. Supporters believe it is necessary if the United States wants to convince other countries that U.S. beef also is safe. Several believe USDA should have gone further. For example, the American Meat Institute (AMI), representing meat packers, had filed a federal lawsuit seeking a preliminary injunction to block enforcement of the continuing ban on imports of Canadian cattle, including those over 30 months old. AMI charged that USDA lacks any scientific basis for continuing to ban such imports. A federal judge in early March 2005 denied the request.

In a February 2005 audit, USDA's OIG concluded that the department's actions on the border opening were sometimes arbitrary and undocumented; policy decisions were poorly communicated to the public and between APHIS and FSIS; and controls over the regulatory process were inadequate. USDA agreed with and promised to implement most of the report's findings.²³ New concerns arose on August 19, 2005, when USDA announced that a Wisconsin meat firm was recalling more than 1,800 pounds of beef products that might contain portions of the backbone of a cow imported for slaughter from Canada that was just over the 30-month age limit under the new rules.

Earlier in 2005, a number of lawmakers had called for a delay or rescission of the Canada rule, and a vote to overturn the rule was successful in the Senate. On March 3, 2005, the Senate approved a resolution of disapproval (S.J.Res. 4) by a vote of 52-46. A related resolution (H.J.Res. 23) was offered in the House, where passage was not considered likely. A final measure would have to be signed by the President, who opposes it.

Other bills addressing the Canada rule include H.R. 187, to prohibit the rule unless access to major markets for U.S. exports of cattle and beef products is "equivalent or better than the access status accorded such exports as of January 1, 2003"; and H.R. 384/S. 108, to prohibit the Canada rule unless mandatory retail country of origin labeling (COOL) is implemented. The current statutorily set deadline for COOL for fresh meats is September 30, 2006. S. 1331 would accelerate the implementation date to January 30, 2006.

A pending bill by the House Agriculture Committee chairman (H.R. 2068) would make COOL voluntary for meats; the House-passed but not the Senate-passed USDA appropriation for FY2006 (H.R. 2744) would prohibit use of funds to implement COOL for meats. Two Senate bills (S. 1300; S. 1333) also would also make COOL voluntary. (See CRS Report 97-508, *Country-of-Origin Labeling for Foods*, by Geoffrey S. Becker.) S. 294 would prohibit imports (from a minimal risk region like Canada) of meat, meat byproducts and meat food products from bovines over 30 months old unless the Secretary reports to Congress that the region "is in full compliance with a ruminant feed ban and other [BSE] safeguards."

²³ USDA, OIG. *Animal and Plant Health Inspection Service Oversight of the Importation of Beef Products from Canada*, on the web at [<http://www.usda.gov/oig/webdocs/33601-01-HY.pdf>].